Eye Care **Evaluation Guide**

NX-IL-BLM-CRD-210005

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Eye Care Evaluation Guide Overview/Instructions

This guide is intended to cover important information related to corneal adverse reactions associated with BLENREP, adverse event management, and instructions to facilitate communication between prescribers and eye care professionals for patients prescribed BLENREP.

PATIENT INFORMATION

Patient name: _____

Date of most recent or scheduled infusion: _____Date of eye care professional appointment:

HAEMATOLOGIST

- Complete your preferred contact information to receive exam results
- Provide this form to patients prescribed BLENREP
- Determine the dose of BLENREP based on recommended dose modifications
- Consult an eye care professional if corneal adverse reactions occur[1]
- Instruct patients to complete patient information
- Instruct patients to bring this form to every eye care professional visit to
- Instruct patients to bring this form to every eye care professional visit to reinforce that ophthalmic exam results should be communicated between the eye care professional and haematologist

HAEMATOLOGIST CONTACT INFORMATION

Name: _____ Phone: _____

Fax: _____ Email: _____

EYE CARE PROFESSIONAL

- Complete your preferred contact information so that the haematologist can contact you if necessary
- Review the form for important information related to ophthalmic exams for patients taking BLENREP
- Return results to the haematologist through secure fax, email, or preferred method to ensure the haematologist can make informed decisions on potential dose modifications or discontinuation in consultation with an ophthalmologist (see grading scale on page 6). Fill out new sections for each follow-up examination

EYE CARE PROFESSIONAL CONTACT INFORMATION

Name: _____ Phone: _____

Fax: _____ Email: _____

MONITOR / MINIMISE / MODIFY

The recommended dose of **BLENREP** is 2.5 mg/kg administered as an intravenous (IV) infusion once every 3 WEEKS until disease progression or unacceptable toxicity[1]

Visual acuity and slit lamp exam should be performed by an eye care professional

1st Dose BLENREP — 3 WEEKS — 2nd Dose BLENREP — 3 WEEKS — 3rd Dose BLENREP — 3 WEEKS — 4th Dose BLENREP

Treatment every 3 WEEKS until disease progression or unacceptable toxicity

Ophthalmic exams and observation of potential ophthalmic symptoms

Ophthalmic Exam Befor e 1st Treatment, before the subsequent 3 treatment cycles, and as clinically indicated whilst ontreatment

Ophthalmic Exam Before 2nd Dose

Ophthalmic Exam Before 3rd Dose

Ophthalmic Exam Before 4th Dose

Advise patients to:

- **Administer preservative-free artificial tear drops** at least 4 times a day beginning on the tsrifday of infusion and continuing until completion of treatment, as this may reduce corneal symptoms For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional
- **Avoid contact lenses until the end of treatment**
- **Use caution when driving** or operating machines
- **Continue monitoring for corneal adverse reactions after treatment and contact haematologist if any symptoms occur**

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Corneal Adverse Reactions Can Be Managed With Dose Modification or Discontinuation as Clinically Warranted

Grading Scale for Corneal Adverse Reactions[1]

Corneal adverse reactions may include findings upon eye examination and/or changes in visual acuity. The treating physician should review the patient's ophthalmic examination report before dosing and should determine the dose of BLENREP based on the highest category from the report in the most severely affected eye, as both eyes may not be affected to the same degree. During the ophthalmic examination, assess the following:

- The corneal examination finding(s) and the decline in best corrected visual acuity (BCVA)
- If there is a decline in BCVA, the relationship of corneal examination findings to BLENREP should be determined
- The highest category grading for these examination findings and BCVA should be reported to the treating physician

Patients should have an ophthalmic examination (including visual acuity and slit lamp examination) performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.

Dose Modifications or Discontinuation May Be Required[1]

Category[a,b]	Eye examination findings	Recommended dose modifications
Mild	*Corneal examination finding(s)* Mild superficial keratopathy[c] *Change in BCVA* Decline from baseline of 1 line on Snellen Visual Acuity	• Continue treatment at current dose
Moderate	**Corneal examination finding(s) Moderate superficial keratopathy[d]** ***Change in BCVA*** **Decline from baseline of 2 or 3 lines (and Snellen Visual Acuity not worse than 20/200)**	• **Withhold treatment until improvement in examination findings and BCVA to mild severity or better** • **Consider resuming treatment at a reduced dose of 1.9 mg/kg**
Severe	*Corneal examination finding(s)* Severe superficial keratopathy[e] Corneal epithelial defect[f] *Change in BCVA* Decline from baseline of more than 3 lines	• Withhold until improvement in examination findings and BCVA to mild severity or better • For worsening symptoms that are unresponsive to appropriate management, consider discontinuation

Corneal Adverse Reactions Have Been Reported With the Use of BLENREP in the DREAMM-2 (Study 205678) Clinical Trial1

- The reported eye disorder adverse reactions (≥3%) were keratopathy (71%), blurred vision events (25%), dry eye events (15%), photophobia (4%), and eye irritation (3%)
- Keratopathy or microcyst-like epithelial changes was characterised as changes in corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eye symptoms
- Patients with a history of dry eyes were more prone to develop changes in the corneal epithelium
- Collection of corneal adverse events included patient-reported adverse reactions and ocular exam findings including best corrected visual acuity (BCVA)
- The median time to onset of Grade 2 or above corneal findings (BCVA or keratopathy on eye examination) was 36 days (range: 19 to 143 days), and the median time to resolution of these corneal findings was 91 days (range: 21 to 201 days)
- Corneal findings (keratopathy) led to dose delays in 47% of patients and dose reductions in 27% of patients. 3% of patients discontinued treatment due to ocular events
- Decreased vision (Snellen Visual Acuity worse than 20/50) in the better eye was reported in 18% of patients and severe vision loss (20/200 or worse) in the better-seeing eye was reported in 1% of patients
- Cases of corneal ulcer (ulcerative and infective keratitis) have been reported. These should be managed promptly and as clinically indicated by an eye care professional. Treatment with BLENREP should be interrupted until the corneal ulcer has healed

Reference
1. BLENREP (belantamab mafodotin) Summary of Product Characteristics.

[a]Note: This guide does not cover all potential adverse reactions and recommended dose modifications.
[b]The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree.
[c]Mild superficial keratopathy (documented worsening from baseline), with or without symptoms.
[d]Moderate superficial keratopathy—with or without patchy microcyst-like deposits, subepithelial haze (peripheral), or a new peripheral stromal opacity.
[e]Severe superficial keratopathy with or without diffuse microcyst-like deposits involving the central cornea, subepithelial haze (central), or a new central stromal opacity.
[f]A corneal defect may lead to corneal ulcers. These should be managed promptly and as clinically indicated by an eye care professional.

Corneal Examination Findings and Best Corrected Visual Acuity

Please refer to page 6 for information on relevant examination findings for BLENREP.

Section 1: For Baseline Examination Only

Date of Assessment: _____

What are the current best corrected visual acuity results (Snellen Visual Acuity)?

OS ___ /___ OD ___ /___

Any pre-existing ocular conditions the prescriber should be aware of:

Mark as applicable:

Right eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Left eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Maximal severity* ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Date: _____

Signature: _____

Doctor's stamp: _____

*** The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree**

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Section 2: Ophthalmic Exam Before 2nd Dose

Date of Assessment: _____

What are the current best corrected visual acuity results (Snellen Visual Acuity)?

OS ___ /___ OD ___ /___

Were there findings upon corneal examination and/or visual acuity assessment? Y / N

If Y, please check affected eyes __ OS __ OD __ OU

Corneal Examination Findings and BCVA Changes From Baseline					
Corneal Examination Findings	**Left Eye** (OS)	**Right Eye** (OD)	**BCVA Changes From Baseline** (on Snellen Visual Acuity)	**Left Eye** (OS)	**Right Eye** (OD)
Check one			Check one		
Mild superficial keratopathy	❑	❑	*No change from baseline*	❑	❑
Moderate superficial keratopathy	❑	❑	*Decline from baseline of 1 line*	❑	❑
Severe superficial keratopathy	❑	❑	*Decline from baseline of 2 or 3 lines*	❑	❑
Corneal epithelial defect	❑	❑	*Decline from baseline of more than 3 lines*	❑	❑
Other _____	❑	❑			

Mark as applicable:

Right eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Left eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Maximal severity* ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Date: _____

Signature: _____

Doctor's stamp: _____

*** The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree**

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Section 3: Ophthalmic Exam Before 3rd Dose

Date of Assessment: _____

What are the current best corrected visual acuity results (Snellen Visual Acuity)?

OS ___ /___ OD ___ /___

Were there findings upon corneal examination and/or visual acuity assessment? Y / N

If Y, please check affected eyes __ OS __ OD __ OU

Corneal Examination Findings and BCVA Changes From Baseline					
Corneal Examination Findings	**Left Eye** (OS)	**Right Eye** (OD)	**BCVA Changes From Baseline** (on Snellen Visual Acuity)	**Left Eye** (OS)	**Right Eye** (OD)
Check one			Check one		
Mild superficial keratopathy	❑	❑	*No change from baseline*	❑	❑
Moderate superficial keratopathy	❑	❑	*Decline from baseline of 1 line*	❑	❑
Severe superficial keratopathy	❑	❑	*Decline from baseline of 2 or 3 lines*	❑	❑
Corneal epithelial defect	❑	❑	*Decline from baseline of more than 3 lines*	❑	❑
Other _____	❑	❑			

Mark as applicable:

Right eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Left eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Maximal severity* ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Date: _____

Signature: _____

Doctor's stamp: _____

* The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree

Section 4: Ophthalmic Exam Before 4th Dose

Date of Assessment: _____

What are the current best corrected visual acuity results (Snellen Visual Acuity)?

OS ___ /___ OD ___ /___

Were there findings upon corneal examination and/or visual acuity assessment? Y / N

If Y, please check affected eyes __ OS __ OD __ OU

Corneal Examination Findings and BCVA Changes From Baseline					
Corneal Examination Findings	**Left Eye** (OS)	**Right Eye** (OD)	**BCVA Changes From Baseline** (on Snellen Visual Acuity)	**Left Eye** (OS)	**Right Eye** (OD)
Check one			Check one		
Mild superficial keratopathy	❑	❑	*No change from baseline*	❑	❑
Moderate superficial keratopathy	❑	❑	*Decline from baseline of 1 line*	❑	❑
Severe superficial keratopathy	❑	❑	*Decline from baseline of 2 or 3 lines*	❑	❑
Corneal epithelial defect	❑	❑	*Decline from baseline of more than 3 lines*	❑	❑
Other _____	❑	❑			

Mark as applicable:

Right eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Left eye: ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Maximal severity* ❑ **Mild** ❑ **Moderate** ❑ **Severe**

Date: _____

Signature: _____

Doctor's stamp: _____

* The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree

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NX-IL-BLM-CRD-210005 October 2021
Produced in Israel
For full information on the medicine, read the MOH approved physician insert, located in the drug database on the Ministry of Health website: www.gov.il/he/service/israeli-drug-index

Requests for medical information should be addressed to il.medinfo@gsk.com
Any suspected adverse events should be reported to the Ministry of Health according to the
National Regulation by using an online form: sideeffects.health.gov.il
Additionally, you should also report to GSK Israel (il.safety@gsk.com)

This booklet and its contents were approved by the Ministry of Health on FEB 2022